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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/644,387	08/23/2000	Gregory E. Agoston	05213-0541	1513

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EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 03/26/2003

JA

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/644,387	Applicant(s) AGOSTON ET AL.	
	Examiner Barbara P. Badio, Ph.D.	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 14-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>14</u> . | 6) <input type="checkbox"/> Other: |

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

2. The rejection of claims 1-13 and 21-25 under 35 USC 103(a) over D'Amato et al. ('074), Clark et al. ('168), Fotsis et al. ('900) or Stewart ('966) is maintained.

Applicant argues (a) the cited references teach away from applicant's invention, (b) the composition of Stewart is not obtainable in high purity and (c) the skilled artisan in the art would expect commercial 2-methoxyestradiol to be impure. Applicant's arguments were considered but not persuasive for the following reasons.

Applicant's argument that the references teach away from the claimed invention is based on the teachings of additional compounds by the cited prior art. For example, D'Amato teaches the concentration of 2-methoxyestradiol needed to inhibit tubulin polymerization by 50% is less than that of estrone. The examiner disagrees that said teaching is a teaching away from removing estradiol from a composition comprising 2-methoxyestradiol. In fact, it would seem to the skilled artisan that the prior art composition consists of a single compound and not a mixture of compounds. However, the only fact obtainable from Table 1 of D'Amato is that 2-methoxyestradiol is more potent than estrone in inhibiting tubulin polymerization. Applicant's arguments against

Art Unit: 1616

the other cited references and the examiner's position are similar to that discussed above.

Applicant also argues that the composition of Stewart is not obtainable in high purity. According to applicant, the compound utilized by Stewart is from Sigma and from a specific lot that had a purity of 98%. First, the examiner notes that Stewart does not disclose that 2-methoxyestradiol was purchased from Sigma nor does it disclose the lot no. as indicated by applicant. Even if one agrees with applicant that the compound was purchased from Sigma, the certificate of analysis from Sigma states "**minimum 98%**" purity by HPLC and ">99.5%" purity by thin layer chromatography for the prior art compound. That would imply that the compound produced by Sigma was obtainable in higher purity by HPLC and TLC. In addition, Table 1 of the present specification indicates that the sample from Sigma was 99.18% pure (i.e., greater than 98% by HPLC, see page 18 of the present specification).

Lastly, applicant argues that the skilled artisan would expect commercial 2-methoxyestradiol to be impure. The examiner does not agree with said assessment because the skilled artisan would have the reasonable expectation that compounds having biological properties and, thus, useful as pharmaceutical agent would be obtained in pure form in order to decrease adverse effect(s) due to impurities. 2-methoxyestradiol is a pharmaceutical agent and would be expected to be in pure form and as evident by the certificate of analysis from Sigma and Table 1 of the present specification, the claimed compound in pure form was known in the art at the time of the present invention. The difference shown in Table 1 of the present specification between

Art Unit: 1616

the compound obtained from Sigma and that of the present specification can be considered within the margin of error (see page 18 of the present specification).

For these reasons and those given in previous Office Actions, the rejection of claims 1-13 and 21-25 under 35 USC 1039a) over D'Amato et al. ('074), Clark et al. ('168), Fotsis et al. ('900) or Stewart ('966) is maintained.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

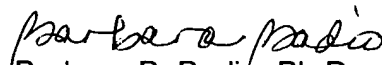
Telephone Inquiry

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

Art Unit: 1616

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
March 25, 2003